

REMARKS

Claims 1-36 were pending in the application. Pursuant to a restriction requirement, applicants elected for prosecution claims 25-31 (Paper No. 6). The Office Action states that claims 1-25 and 32-36 are withdrawn from consideration, and applicants assume this is a typographical error, as claim 25 is within the elected group and therefore has not been withdrawn from consideration.

Rejections Under 35 USC § 112, First Paragraph (Written Description)

Claims 25-31 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which is not described in the specification in a manner that reasonably conveys to one skilled in the art that the inventors were in possession of the claimed invention at the time the application was filed. The Patent Office asserts, first, that the specification only describes Arabidopsis plants transformed with a polynucleotide encoding ABI5 under the control of the CaMV 35S promoter." Office Action at 3. Second, the Patent Office asserts that "the structure of the polynucleotide [ABI5] is not explicitly disclosed in the specification." Id. Finally, the Patent Office asserts that a disclosure of an ABI5 polynucleotide from Arabidopsis that confers sensitivity to abscisic acid-induced inhibition of seed germination and root growth when expressed in transgenic Arabidopsis seeds does not provide an adequate description of the claimed genus, which the Patent Office asserts "encompasses a multitude of different nucleotide sequences, including those yet to be discovered." Id. The Patent Office asserts, without providing any supporting evidence or reasoning, that "in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus." Id.

Applicants respectfully submit that this rejection is in error. The written description requirement of § 112, first paragraph, does not require that each and every embodiment, or even a "substantial number" of the embodiments be explicitly described in the specification. The Federal Circuit has stated that "if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if not every nuance of the claims is explicitly described in the specification, then the adequate written description requirement is met." In re Alton, 37 U.S.P.Q. 2d, 1578

(Fed. Cir. 1996). Put another way, this requirement is satisfied when “one skilled in the art, reading the original disclosure, [can] immediately discern the limitation at issue in the claims.” Purdue Pharma LP v. Faulding, Inc., 56 U.S.P.Q. 2d 1481 (Fed. Cir. 2000). The present specification expressly states that “results are presented which show that ABI5 expression is involved in tolerance of plants to stress such as drought and high salt.” And that “overexpression of ABI5 inhibits germination of seeds during times of stress.” Specification, page 2. The applicants further describe the physiological effects of overexpressing ABI5. Specification, page 4, lines 19-28. This conclusion is supported by several lines of evidence summarized in the specification at page 6, lines 9-27. The specification furthermore clearly indicates that the discoveries of the inventors led them to the invention of methods for delaying germination, etc. of seeds, and of conveying drought resistance to seeds, seedlings and plants in general by overproducing ABI5 in general (not limiting their description of the invention to Arabidopsis genes expressed in transgenic Arabidopsis only). Specification, page 8, lines 4-11. There is extensive description in the specification of the scope of possible uses of the invention in agriculture, without any limitation to species source of the ABI5 gene or of the species in which said gene would be expressed. Specification, page 16, line 28 - page 18, line 24. Finally, the original claims filed in this application are explicitly not limited as to species, either as a source of the ABI5 gene or as a host thereof. The specification therefore very clearly describes what the inventors claim to have invented, as well as its meets and bounds, and there is no limitation therein to Arabidopsis ABI5, or transgenic Arabidopsis.

Regarding the assertion that the structure of the ABI5 polynucleotide “is not explicitly disclosed in the specification” (Office Action at 3), applicants direct the examiner’s attention to page 1, lines 21-33 of the specification, which describe previous work with ABI5 and gives journal citations where the relevant structural information can be found in the prior art. This is sufficient to satisfy the requirements of § 112. Hyatt v. Boone, 47 U.S.P.Q. 2d 1128 (Fed. Cir. 1998).

The guidelines established by the U.S. Patent and Trademark Office for examining the written description requirement clearly state that “there is a strong presumption that an adequate written description of the claimed invention is presented when the application is filed.” 66 Fed. Reg. 1105 (first column). The guidelines also admonish that “the examiner has the initial burden of presenting by a

preponderance of the evidence why the person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description. 66 Fed. Reg. 1107 (second column). The guidelines make clear that the written description requirement of the first paragraph of § 112 focuses on whether or not the specification adequately communicates to a person of ordinary skill in the art that the claims are commensurate in scope with what has been invented. This specification undoubtedly does so, as it uses terms to describe the invention which are identical in scope and nature to the terms used in the claims to set forth the meets and bounds of the claimed invention.

The most recent pronouncements of the Federal Circuit on the written description requirement fully support this conclusion. In Amgen, Inc. v. Hoechst Marion Roussel, Inc. et al., 65 U.S.P.Q. 2d 1385 (Fed. Cir., 2003), the Federal Circuit stated that "the purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to 'recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'" 65 U.S.P.Q. 2d at 1397 (quoting Vast-Cath Inc. v. Mahurkar, 19 U.S.P.Q. 2d 1111, 1115 (Fed. Cir. 1991)). What the Federal Circuit does not state is that the written description must convey to the person of ordinary skill in the art that the inventor has conceived of each and every means of how his invention is to be carried out. This is not necessary even under the enablement requirement of § 112. The Amgen case is particularly relevant here because one of the asserted grounds of the patentees' failure to comply with the written description requirement in that case was their failure to "sufficiently describe the use of all vertebrate and mammalian cells." Id. This is precisely the point made by the Patent Office in the present rejection, that the specification does not describe the use of all of seeds, seedlings or plants encompassed within the scope of the claims. As the Federal Circuit makes clear in Amgen, such detail is not required for compliance with the written description requirement of § 112, first paragraph. The Federal Circuit quoted with approval the lower court's statement that:

When the claim is to a composition rather than a process, the written description requirement does not demand that the specification describe technological developments in the way in which a claimed composition is made that may arise after the patent application is filed. [Citations omitted]. Instead, § 112 only requires the court to determine whether the specification conveys to

one of ordinary skill in the art that as of [the filing date of the application] that [the inventor] invented the subject matter claimed in the patents in suit. [Citations omitted]. The written description inquiry, therefore, focuses on a comparison between the specification and the invention referenced by the terms of the claim – not comparison between how the product was made as disclosed in the patent or future developments of this process that might alter or even improve how the same product is made.”

65 U.S.P.Q. 2d at 1397-98 (quoting the District Court at 57 U.S.P.Q. 2d, 1449, 1508 (D. Mass. 2001)).

Thus, the fact that the inventors have not described, or reduced to practice, every possible embodiment of their invention (including embodiments based on potential future developments in the technology) does not negate compliance with the written description requirement of § 112, first paragraph. For the foregoing reasons, applicants respectfully submit that this rejection is not warranted, and request that it be reconsidered and withdrawn.

Rejection Under 35 USC § 112, First Paragraph (Enablement)

The Patent Office has rejected claims 25-31 under 35 USC § 112, first paragraph, because the specification, “while enabling for a seed, seedling, or plant transgenic for an ABI5 polynucleotide obtained from Arabidopsis (gene bank Accession AC006921) that overproduces the encoded Arabidopsis ABI5 polypeptide . . . [it] does not reasonably provide enablement for a seed, seedling, or plant transgenic for any ABI5 polynucleotide and that is resistant to drought stress or salt stress.” Office Action, page 3-4. The Patent Office stated that the description in the specification, which discloses transgenic Arabidopsis plants hypersensitive to abscisic acid-induced inhibition of seed germination and root growth relative to non-transformed Arabidopsis plants, “does not disclose whether seed, seedlings, or plants that are transgenic for Arabidopsis ABI5 are resistant to drought or to high salt as compared to non-transgenic seed, seedlings, or plants.” Office Action at 4. The Patent Office asserts that it would require undue experimentation for one skilled in the art to determine “how to express a polynucleotide encoding ABI5 such as that the transgenic seed, seedlings or plants would be resistant to drought or high salt, because the ability of such a polynucleotide to confer drought or high salt resistance to transgenic seed, seedlings, or plants is unpredictable.” Office Action at 4-5. The Patent Office then lists several hypothetical situations wherein these difficulties might arise. Office Action at 5.

The applicants respectfully submit that this rejection is improper and request that it be reconsidered and withdrawn. All that is required to meet the enablement requirement of § 112, first paragraph is objective enablement. In re Marzocchi, 169 U.S.P.Q. 2d 367 (C.C.P.A. 1971). Furthermore, a specification disclosure is presumed true and accurate, and in compliance with the enablement requirement of the first paragraph of § 112 unless "there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 169 U.S.P.Q. at 369. As the Marzocchi court stated,

It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in the supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise there would be no need for the applicant to go through the trouble and expense of supporting his presumptively accurate disclosure.

169 U.S.P.Q. at 370.

First, the Patent Office has provided no evidence or reasoning to rebut the presumptive accuracy of the specification disclosure. "The Patent Office may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis." In re Warner, 154, U.S.P.Q., 173, 178 (C.C.P.A. 1967). The present specification provides sufficient detail for persons of ordinary in the art to identify ABI5 sequences for use in the invention (an Accession No. for one ABI5 sequence is provided, as well as citations to journal articles disclosing various ABI genes). See Specification page 1, lines 16-20. The specification also directly refers to the role of abscisic acid (ABA) in a plant's response to stress, particularly water deprivation (which is well known to be a principle causative factor in salt damage to plants – disruptions of the osmotic potential across plant cell membranes causes net loss of water to the plant). The specification also makes express reference to prior art knowledge of the "physiological role of ABA and mechanisms of action triggered by ABA during germination and early seedling growth." Specification at page 1, lines 21-22. Finally, the experimental evidence presented in the specification demonstrates that ABA regulates ABI5 accumulation and that transgenic plants overexpressing ABI5 are hypersensitive to ABA with respect to both germination and vegetative growth. See, e.g., Specification, page 4, lines 19-23. In view of the known link between ABA and initiation and maintenance of seed dormancy, and the plant's

response to water stress, coupled with the experimental evidence of the role of ABA in ABI5 accumulation, and the hypersensitization to ABA caused by overexpressing ABI5 with respect to germination and vegetative growth, it is logical to conclude that the hypersensitization to ABA caused by overexpression of ABI5 can make a plant hyper-responsive in all of the physiological processes in which ABA is involved. This conclusion is further supported by the experimental evidence showing induction of ABI5 by drought and high salt stress, and the resistance to drought of seedlings of plants overexpressing ABI5.

Specification at page 14. All of the methods needed for identifying ABI5 genes, transfecting plants to overproduce the ABI5 gene, and assessing their resistance to drought and salt stress are set out in detail in the examples of the specification. The specification thus provides not only technical details sufficient to enable at least one embodiment of the claimed invention, it also provides evidence and theoretical basis for the functioning of the claimed invention.

The Patent Office has asserted that it would require undue experimentation for a person of ordinary skill in the art to practice the claimed invention throughout its scope. First, applicants wish to point out that claim 25 is directed to a seed, seedling or plant which is transgenic for ABI5, and claims 26-28 specify embodiments relating to the nature of the promoter used, that the plant etc. overproduces ABI5, and that the plant etc. is hypersensitive to abscisic acid. The specification expressly enables the production of such seeds, seedlings and plants through the provision of working examples showing actual reduction to practice of these claimed seeds, seedlings and plants expressing an introduced ABI5 gene (i.e., that are transgenic for ABI5). "The enablement requirement is met if the description enables any mode of making and using the claimed invention." Engel Industries, Inc. v. Lock Former Company, 20 U.S.P.Q. 2d, 1300, 1304 (Fed. Cir. 1991). A specification is considered to be in compliance with the enablement requirement of the first paragraph of § 112 if it contains such an enabling disclosure; the applicant need not describe all actual embodiments. MPEP § 2164.02. The fact that some experimentation may be required to practice some embodiments, (i.e., some species, or some specific ABI5 genes), something that the Patent Office has not established in any event, does not indicate that the claims are not enabled. The Court of Claims and Patent Appeals characterized "undue experimentation" as experimentation that would "require ingenuity beyond that to be expected of one of ordinary skill in the art" (In re Angstadt and Griffin, 190

U.S.P.Q., 214, 218 (C.C.P.A. 1976)) and the Board of Patent Appeals and Interferences has elaborated on this definition as follows:

"The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed."

Ex parte Jackson, 217 U.S.P.Q. 804, 807, (B.P.A.I. 1982). The key is "undue" not "experimentation." In re Wands, 8 U.S.P.Q. 2d, 1400 (Fed. Cir. 1998).

The Patent Office has provided nothing other than speculation regarding potential difficulties in carrying out specific embodiments of the claimed invention. The Patent Office concedes that "one of skill in the art could readily make seed, seedlings, or plants that are transgenic for any ABI5 polynucleotide." Office Action, page 5. This issue is dispositive of the enablement of claims 25-28, which as has already stated, recite seed, seedlings or plants which are transgenic for ABI5, and various specific embodiments thereof per se, which are expressly enabled by the working examples of this specification. It is pure speculation on the part of the Patent Office that one of ordinary skill in the art would require undue experimentation in order to determine which ABI polynucleotide to express such that the transgenic seed, seedlings, or plants would exhibit increased sensitivity to abscisic acid as required by claim 29. Office Action at 5. The mere assertion that the art is unpredictable is not sufficient to establish lack of compliance with the enablement requirement of § 112, first paragraph. In re Warner, 154, U.S.P.Q. 173, 178 (C.C.P.A. 1967) (The burden is on the Patent Office to supply the factual basis for its objection, and it may not resort to speculation, assumptions, or hindsight.); see also In re Marzocchi, 169 U.S.P.Q. at 370. With regard to claims 30 and 31, specifying resistance to drought and resistance to high salt, the specification, as already discussed, provides detailed methodologies for producing transgenic plants, and for screening them for tolerance to water stress (which is the primary cause of drought and salt damage to plants). Though some experimentation may be required in producing specific embodiments, the Patent Office has presented no evidence that such experimentation would be anything but routine to a person of ordinary skill in the art who has been provided with the guidance set forth in this specification, and applicants submit that indeed any such experimentation would not be other than routine. For the

foregoing reasons applicants respectfully submit that this rejection is improper, and request that it be reconsidered and withdrawn.

Rejections Under 35 USC, § 112, Second Paragraph

The Patent Office has rejected claims 25-28 as being indefinite in the recitation of "ABI5," as the meaning of the acronym is allegedly unclear. Applicants direct the Examiner's attention to the specification at page 1, line 16, where the acronym ABI is defined as "ABA [i.e., abscisic acid] insensitive", as well as lines 22-33, which discuss in detail the identification and analysis of the ABI gene designated "ABI5." Applicants submit therefore that the term ABI5 is fully and adequately described and defined in the specification such that its use in the claims does not render them indefinite.

The Patent Office has further rejected claim 25 as indefinite in the recitation of "transgenic for ABI5", inquiring whether or not it means that the gene for ABI5 has been inserted into the plant. Applicants have amended claim 25 to recite "a seed, seedling, or plant expressing an ABI5 transgene". This is believed to clarify the asserted ambiguity. Support for this amendment is found in the specification at page 15, lines 9-22, wherein are described "transgenic Arabidopsis lines expressing ABI5", and at page 16, lines 17-26 describing ABI5 – 4 "lines expressing the 35S:: ABI5 transgene."

The Patent Office has also rejected claims 26 and 27 as indefinite in the recitation of "gene." Applicants respectfully submit the word "gene" is as definite as the subject matter permits. Shatterproof Glass Corporation v. Libby-Owens Ford Company, 225 U.S.P.Q. 634, 641 (Fed. Cir. 1985). ("If the language is as precise as the subject matter permits, the courts can demand no more".) Applicants believe that limiting the claims to "isolated" sequences unduly limits the scope of the claims. For example, it is possible to transpose genes already within a plant's genome to other locations within the genome where they are expressed at higher levels, as well as to insert an activator or promoter to be operatively linked to an endogenous gene such that the expression of that gene is altered (for example to become inducible, or repressible, or enhanced). The invention of claim 26 and 27 thus is not limited strictly to genes that were "isolated". Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claim 27 has been rejected as indefinite in the recitation of "activatable." Applicants direct the Examiner's attention to the specification at page 7, lines 24-26, where an "activatable promoter" is defined as "a promoter which is made active by adding a component which causes a gene under the control of said promoter to become active." The definition is expressly stated to comprise both inducible and de-repressible promoters.


Claims 28-29 have been rejected as indefinite for the use of the terms "overproduces" and "hypersensitive", which are asserted to be relative terms that lack comparative basis. Applicants direct the Examiner's attention to the specification at page 7, line 27 through page 8, line 10, where the terms "hypersensitive" and "overproduces" are defined with precision, and at length.

Claims 30 and 31 have been rejected as indefinite in the recitation of "resistant" as a relative term that lacks comparative basis. These claims have now been amended to recite "drought tolerant" and "tolerant to high salt", terms which are specifically defined in the specification at page 7, lines 14-21. Claim 31 has been rejected as indefinite in the recitation of "high" as a relative term that lacks comparative basis. Applicants direct the Examiner's attention to the specification at page 7, lines 22-23 where the term "high salt" is given a precise definition as used in the context of the present invention, i.e., "a salt concentration equal to or greater than 200% of the salt concentration of Murashige and Skoog medium."

In view of the foregoing remarks and amendments, applicants submit that use of the terms in question in the present claims does not render them indefinite, and respectfully request that the rejections of the claims under the second paragraph of 35 USC § 112 be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, applicants submit that the claims as amended are in full compliance with all the requirements of 35 USC § 112, and respectfully request that the rejections thereunder be reconsidered and withdrawn. Favorable action on the claims is earnestly solicited.

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